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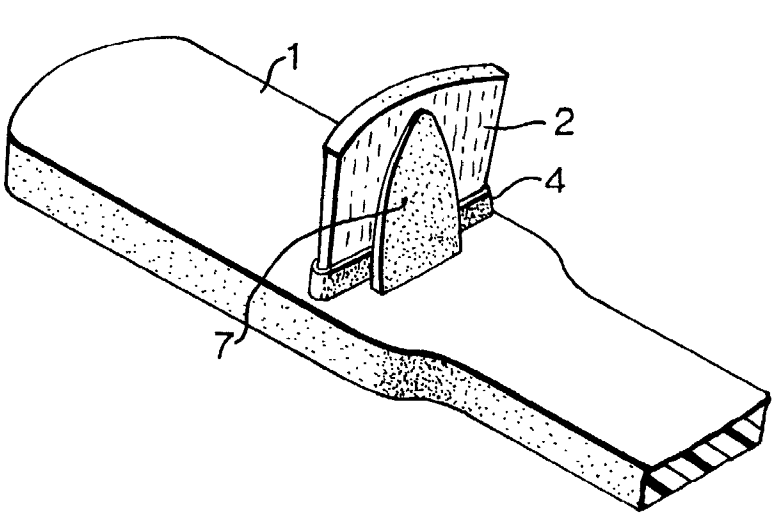
(54) **Title:** TOOTHBRUSH



(57) **Abstract:** Toothbrush comprises a handle and a head for improved cleaning to the interdental regions of the teeth, said head comprising a linear arrangement of bristles transverse to the general longitudinal axis of the brush and extending along a length equal to or greater than a third of the width of the toothbrush head at the location of the arrangement, characterised in that a portion of the bristles at either end of the arrangement are angled away from the vertical such that the arrangement presents a fan-shaped transverse brushing array.

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TOOTHBRUSH

The present invention relates to a toothbrush comprising a handle and a head for improved cleaning to the interdental regions of the teeth, said head comprising a linear arrangement of bristles transverse to the general longitudinal axis of the brush and extending along a length equal to or greater than a third of the width of the toothbrush head at the location of the arrangement.

US 1 191 556 (Blake) details a toothbrush consisting of the usual tuft bristle formation interspersed with flexible blades.

WO 99/01054 outlines a toothbrush with flexible fin structures that aid in the cleaning process by penetrating the interproximal region of teeth.

US 5 392 483 details a patent application with normal bristle tufts in which the terminal tufts of the toothbrush are inclined away from each other.

US 3 295 156 discloses individual tufts fan but not a confluent linear array of bristles.

According to the present invention, there is provided a toothbrush comprising a handle and a head for improved cleaning to the interdental regions of the teeth, said head comprising a linear arrangement of bristles transverse to the general longitudinal axis of the brush and extending along a length equal to or greater than a third of the width

of the toothbrush head at the location of the arrangement, characterised in that a portion of the bristles at either end of the arrangement are angled away from the vertical such that the arrangement presents a fan-shaped transverse brushing array.

Preferably the linear arrangement presents a fan-shaped brushing array which is comprised of a row of individually fixed bristle tufts.

The bristle tufts making up the fan-shaped brushing array may suitably be fixed to the brush head by so called anchor technology whereby the bristle tufts are bent in half by a strip of metal which is pressed into the wall surrounding the tuft hole.

Alternatively the tufts may be fixed to the brush head by in-mould welding. This is a newer technique which involves the moulding of the brush head around a fixed bristle tuft.

The bristle tuft holes used to fix the bristle tufts to the head are suitably dimensioned to provide for the formation of a fan-shaped brushing array. Preferably, this means that the tuft holes are located close to one another and in a linear arrangement. More preferably, the bristle tuft holes are square or rectangular in shape. Where they are rectangular they consist of a pair of opposing long wall faces and a pair of opposing short wall faces with the array of holes arranged such that the long wall faces are substantially aligned. Preferably the long faces are greater in length than the short faces, more preferably, the long

faces are from 1.01 to 1.2 times the length of the short faces. Preferably, the short faces are aligned with the general longitudinal axis of the brush head. In this way the confluence of the individual bristle tufts in the fan-shaped brushing arrays can be maximised.

In a more preferred embodiment the holes at the two edges of the transverse linear arrangement when viewed from above are tapered such that the edge of the fan presents a softened wall. This reduces the hard nature of bristle tufts which protrude beyond the normal brushing surface.

The linear arrangement brushing elements according to the invention are fan-shaped. This means that viewed from the tip end of the brush down towards the handle the transverse array presents a wall of bristle tufts which is narrower at the bottom than at the top, i.e. the bristle brushing area is greater than the area of the tufts holes and extends laterally beyond the end holes.

Preferably, a portion of the bristles within the fan-shaped brushing array are angled with respect to the vertical. Preferably, these bristles area angled away from the centre line along the longitudinal axis of the brush head. Preferably, the fan-shaped brushing array is dimensioned such that the ends of the fan-shaped array are angled at from 0.5° to 30° from one another, more preferably from 5° to 25° and especially from 13° to 22°.

In a preferred embodiment the bristles at the ends of the linear arrangement which are angled comprise a portion

amounting to from 0.5 to 30% of the bristles within the linear fan-shaped array. More preferably, from 3 to 25% and especially from 10 to 20% of the bristles in the fan-shaped linear arrangement are angled.

In another preferred embodiment the brushing surface of the fan-shaped array is arcuate when viewed from the tip of the brush down towards the handle. Preferably, the brushing surface of the fan-shaped array is arcuate in the sense that it extends further from the brush head in the middle of the array and gradually less so at the ends.

In a preferred embodiment the brush according to the invention comprises further bristles which may or may not be arranged in bristle tufts as is the usual fashion in toothbrush technology. These 'conventional' bristles provide additional cleaning to the teeth in use. Typically these conventional bristles extend an average length l from the brush head to a tip. Preferably, the bristles making up the fan-shaped array extend a length ranging from 1 to 1.5 l, more preferably from 1.05 to 1.4 l and especially preferably from 1.1 to 1.35 l. This relationship between the lengths of the bristles in the fan-shaped array and other, conventional bristles on the brush head provides a synergistic cleaning of the teeth during use. The fan-shaped arrays excise the debris from the interdental regions and the conventional bristles remove the debris from the dentition such that it can be removed from the oral cavity during expectoration.

In a further preferred embodiment the bristles in the fan-shaped array are more flexible than those in the

conventional tufts. This flexibility is not just due to the longer length but also because of the more flexible nature of the materials used. It may also be due to the reduced diameter of the bristle filaments in the fan-shaped array. Preferably the diameter of the bristle in the fan-shaped array ranges from 0.75 to 0.99 that of the bristles in the conventional bristles, more preferably from 0.85 to 0.95 and especially preferably from 0.9 to 0.95 that of the conventional bristles.

In a further preferred embodiment the fan-shaped array is supported on the brush head by a supporting boot. Such supporting boots are known in the prior art, for example in EP 0 888 072 (M+C Schiffer).

In a preferred embodiment such supporting boots compress the fan-shaped arrays such that the bristle tufts present a more concentrated brushing surface without compromising the fan-shaped arrangement. More preferably, the compression occurs in an axis aligned to the general longitudinal axis of the brush head. In the alternative the compression may also occur in a direction substantially transverse the general longitudinal axis of the brush head. In this way the compression slightly reduces the angle of the angled bristles at the edges of the fan-shaped array but this also assist in concentrating the bristles at their brushing ends.

In a more preferred embodiment the boots have an end on profile substantially similar to the profile of the fan-shaped array also in end on view. In other words it is

preferred that the profile of the boots is also arcuate being higher in the middle than at the edges.

It is also preferred that each individual boot encompasses an entire fan-shaped array so that the fan shaped array does not lose its confluent bristle presentation.

The boots are typically moulded out of an elastomeric material which provides some elasticity to the supporting role of the boot. Suitable elastomers are well known in the art to the person skilled in plastics manufacture.

In an alternatively preferred embodiment the brush according to the invention comprises a rubbery tooth pick device for cleaning further the interdental regions of the teeth. While tooth picks are known in brushes they are not known in combination with the fan-shaped bristle arrays as defined herein. We have surprisingly found that the cleaning efficacy of the toothpicks is markedly improved with the combination of picks and fan-shaped arrays since the fan-shaped arrays loosen the hard to remove material stuck between the teeth and the picks are then able to remove said matter more easily.

Preferably, said pick is a flattened structure with flattened faces lying transverse the general longitudinal axis of the brush head. Accordingly, the pick is thus substantially bendable in a direction of motion along the general longitudinal axis of the brush head and less so in a direction transverse the general longitudinal axis of the brush head. This means that the pick has less resilience and

thus greater cleaning efficacy when bent in a direction transverse the longitudinal axis of the brush head than when bent in a direction along said axis. This allows the picks to get between the teeth and prise out the hard to remove material when the brushing direction is up and down (in a direction transverse the general longitudinal axis of the brush head) rather than side to side. In a side to side motion the pick provides a tooth polishing effect as it rubs over the surface of the tooth.

In a preferred embodiment the pick is ellipsoidal in shape towards the tip end of the pick. Said ellipsoidal shape provides the maximum cleaning efficacy without harming the gums. A pointed shape would harm the gums and a fully rounded shape would not be able to focus the pressure in the tip sufficiently to remove fastened debris from between the teeth.

Said picks are suitably made from an elastomeric material similar to the material of the boots and these are commercially available in many different forms which are well known to the man skilled in the art. Accordingly, the behaviour of the picks can be modified by the man skilled in the art by careful consideration of the physical properties of the elastomeric materials.

Specific embodiments of the invention will now be described by way of example with reference to the accompanying drawings in which:

Figure 1 is a side elevational view of part of a brush head according to the invention;

figure 2 is an end on view of the same brush head;

figure 3 is a side elevational view of part of a brush head according to the invention;

figure 4 is a perspective view of part of a brush head according to the invention;

figure 5 is a plan view of part of a brush head according to the invention;

figure 6 is a plan view of part of a brush head according to the invention;

figure 7 shows part of a brush head in perspective view; and

figure 8 shows a brush head in elevational view.

In more detail, figure 1 discloses a brush head (1) comprising a fan-shaped brushing array (2). In this view the fan-shaped array (2) cannot be perceived as a fan-shaped array since it is transversely located on the brush head and is seen end on. The figure only shows the fan-shaped array and not any of the other features of the brush head for the sake of clarity. Other features may also be present as described herein without affecting the nature of the fan-shaped array.

Figure 2 discloses the brush head according to figure 1. Shown is a brush head (1) and a fan-shaped array (2). The bristles at the edges of the fan-shaped array are angled away from the vertical by $\alpha°$. The bristles at the centre of the fan-shaped array are substantially vertical with respect to the brush head. Again, the figure only shows the fan-shaped array and not any of the other features of the brush head for the sake of clarity. Other features may also be present as described herein without affecting the nature of the fan-shaped array.

Figure 3 is a brush head comprising three fan-shaped arrays (2). Starting from the tip end of the brush head the first fan-shaped array is a distance *a* from the second fan-shaped array. The second array is located at a distance *b* from the third array. Distance *b* is typically from 0.5 to 1.1 times *a*, preferably from 0.6 to 0.9 and especially preferably from 0.7 to 0.8 times *a*. These values are applicable in any embodiment of the invention comprising three fan-shaped arrays. Once again the figure only shows the fan-shaped arrays for the sake of clarity.

Figure 4 is a perspective view of a brush according to the invention. Shown is a fan-shaped array (2) which is supported by a supporting boot (4). Said boot extends from the brush head up to from 5 to 30% of the full extent of the average bristle height in the array. Preferably, it extends to from 10 to 25% the height. These values being applicable for any brush according to the invention which comprises supporting boots. Once again the figure only shows the fan-shaped array in a boot for the sake of clarity.

Figure 5 shows a brush head comprising a row of tuft holes which are capable of housing a fan-shaped array. Shown are four bristle tuft holes (5) which have a length *c* and a width *d* which define a rectangular

Figure 6 shows a brush head similar to that in figure 5 but comprising a pair of lateral tufts holes (6) which are tapered towards the edge of the brush head.

Figure 7 discloses a brush head comprising a fan-shaped array (2) and a tooth cleaning pick (7). Said pick (7) is ellipsoidal in shape and flattened in a direction substantially along the general longitudinal axis of the brush head.

Figure 8 discloses an elevational view of a toothbrush according to the invention. Shown are a brush head comprising three longitudinally spaced fan-shaped arrays (2), three longitudinally spaced picks (7) and conventional bristle tufts (8) there between. The conventional bristle tufts extend a length *l* from the brush head and the fan-shaped arrays extend a distance greater than *l* from the brush head. The picks are located between said fan-shaped arrays and the latter are disposed within supporting boots (4). The bristles making up the fan-shaped arrays do not extend longitudinally beyond the supporting boot's perimeter contour.

CLAIMS

1. Toothbrush comprising a handle and a head for improved cleaning to the interdental regions of the teeth, said head comprising a linear arrangement of bristles transverse to the general longitudinal axis of the brush and extending along a length equal to or greater than a third of the width of the toothbrush head at the location of the arrangement, characterised in that a portion of the bristles at either end of the arrangement are angled away from the vertical such that the arrangement presents a fan-shaped transverse brushing array.

2. Toothbrush according to claim 1, wherein the linear arrangement comprises a row of individually fixed bristle tufts.

3. Toothbrush according to claim 1 or 2, wherein the portion of bristles at either end of the linear arrangement are angled at from 0.5° to 20°.

4. Toothbrush according to any preceding claim, wherein the angled portion of bristles at either end of the linear arrangement constitutes from 0.5% to 30% of the total number of bristles in the arrangement.

5. Toothbrush according to any preceding claim, wherein a brushing edge of the linear arrangement is arcuate.

6. Toothbrush according to any preceding claim, wherein the linear arrangement is supported by a supporting boot.

7. Toothbrush according to claim 6, wherein the boot compresses the linear arrangement in a direction transverse the general axis of the linear arrangement.

8. Toothbrush according to any preceding claim, wherein the brush also comprises rubbery picks.

Fig.1.

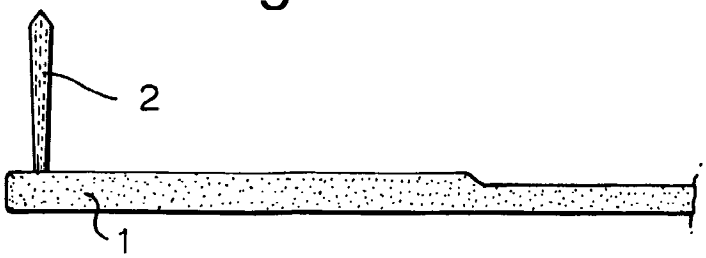


Fig.2.

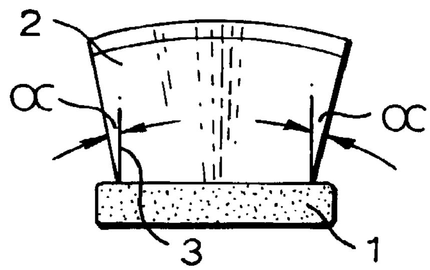


Fig.3.

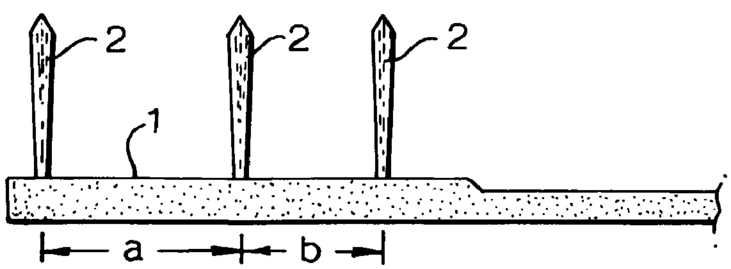


Fig.4.

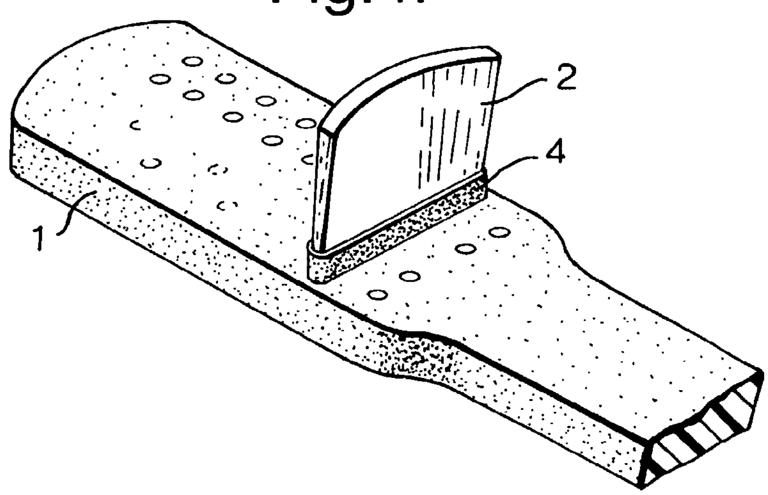


Fig.5.

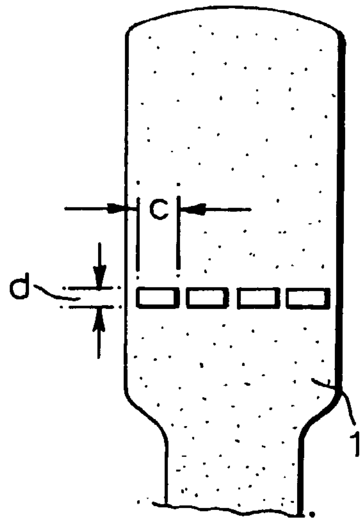


Fig.6.

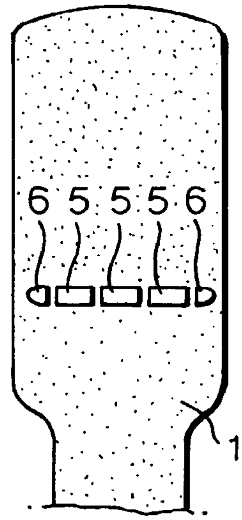


Fig.7.

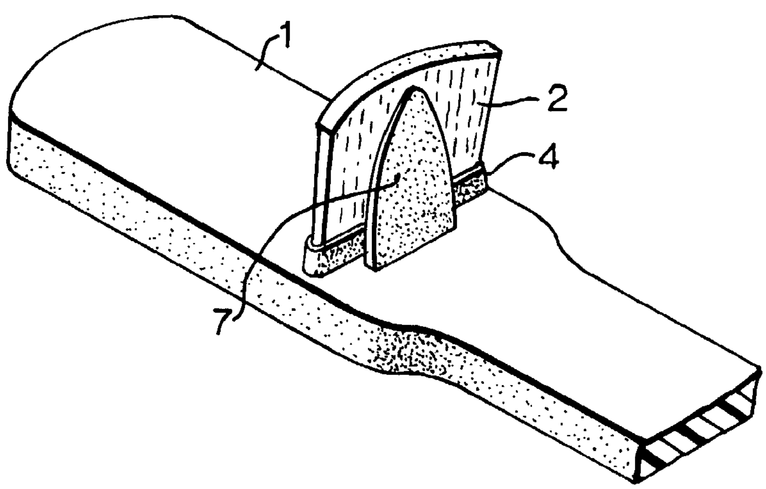
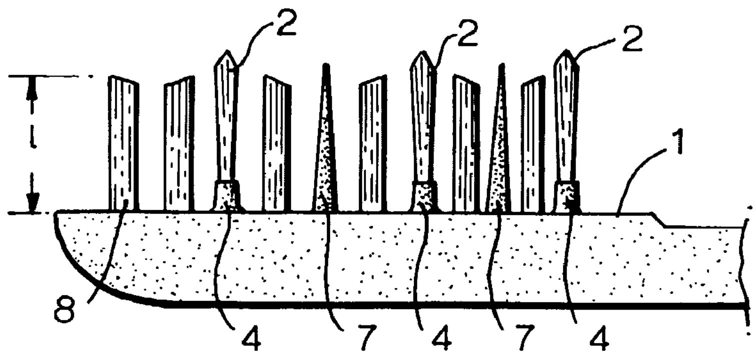


Fig.8.



INTERNATIONAL SEARCH REPORT

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A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 A46B9/04 A46B9/12

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 A46B

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
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Y	the whole document	6-8

Y	DE 41 01 366 A (VUKOSAVLJEVIC JOVICA) 8 August 1991 (1991-08-08)	6,7
A	the whole document	1,2

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A	the whole document	1,2

X	US 3 103 679 A (CLEMENS GEORGE S) 17 September 1963 (1963-09-17)	1-3,5
Y	the whole document	8

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[X] Further documents are listed in the continuation of box C.

[X] Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance

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"&" document member of the same patent family

Date of the actual completion of the international search	Date of mailing of the international search report
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Name and mailing address of the ISA	Authorized officer
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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication,where appropriate, of the relevant passages	Relevant to claim No.
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International Application No
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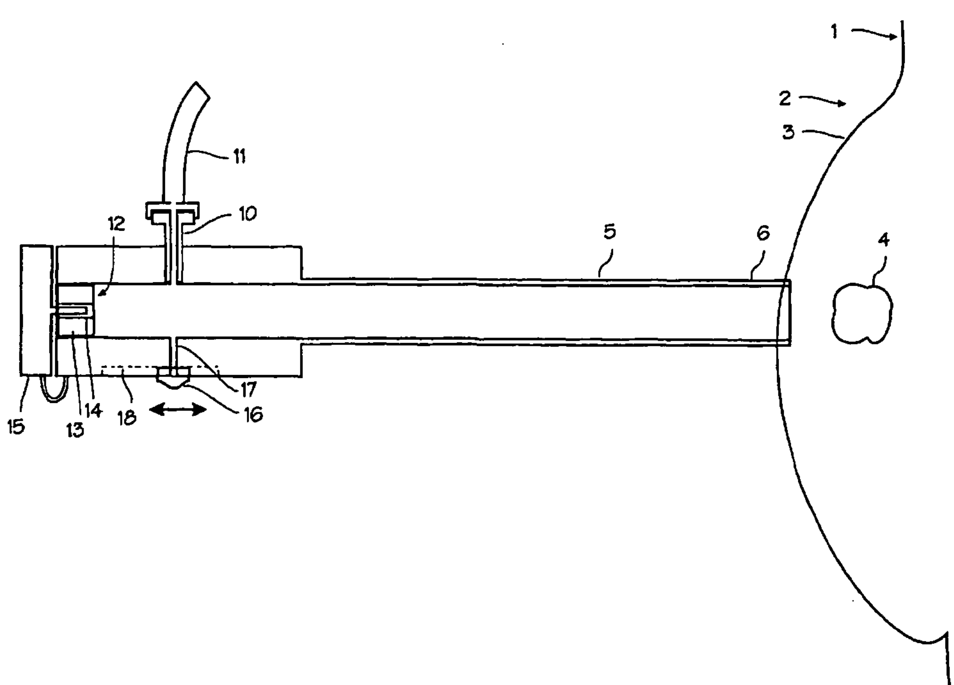
(54) Title: DEVICE FOR BIOPSY AND TREATMENT OF BREAST TUMORS



(57) Abstract: A device for diagnosis and treatment of tumors and lesions within the body. A cannula (5) adapted to apply suction through the lumen (22) of the catheter to the tumor or lesion is described. The lumen (22) has a self sealing valve (12) through which a cryoprobe (27) is inserted while the suction is being applied. The cryoprobe (27) is then inserted into the lesion, and operated to ablate the lesion.

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Device for Biopsy and Treatment of Breast Tumors

Field of the Inventions

The devices and method described below relate to the diagnosis and treatment of breast lesions, and more generally, to the diagnosis and treatment of tumors and lesions throughout the body.

Background of the Inventions

Biopsy is an important procedure used for the diagnosis of patients with cancerous tumors, pre-malignant conditions, and other diseases and disorders. Typically, in the case of cancer, when the physician establishes by means of procedures such as palpation, mammography or x-ray, or ultrasound imaging that suspicious circumstances exist, a biopsy is performed. The biopsy will help determine whether the cells are cancerous, the type of cancer, and what treatment should be used to treat the cancer. Biopsy may be done by an open or percutaneous technique. Open biopsy, which is an invasive surgical procedure using a scalpel and involving direct vision of the target area, removes the entire mass (excisional biopsy) or a part of the mass (incisional biopsy). Percutaneous biopsy, on the other hand, is usually done with a needle-like instrument through a relatively small incision, blindly or with the aid of an imaging device, and may be either a fine needle aspiration (FNA) or a core biopsy. In FNA biopsy, individual cells or clusters of cells are obtained for cytologic examination and may be prepared such as in a Papanicolaou smear. In core biopsy, as the term suggests, a core or fragment of tissue is obtained for histologic examination which may be done via a frozen section or paraffin

section. One important area where biopsies are performed is the diagnosis of breast tumors.

Traditionally, the biopsy technique for breast tumors involves placing a biopsy device multiple times into the breast and taking several samples of tissue from a mass or tumor which is suspected of being cancerous. Several samples are required to be sure that some tissue from the suspect mass has been captured, and enough tissue has been sampled to ensure that, if disperse cancer cells exist in the suspect mass some of those cancer cells will be captured in the samples. Each time the device is placed the physician must locate and direct the device with ultrasound imaging into the correct position near the suspect mass. Some breast tumors and lesions are very well defined, hard spherical masses which grow within the soft, compliant breast tissue. It is difficult to force a needle into these lesions because they are resistant to puncture and fairly mobile. Forcing the biopsy needle into the lesion is like trying to spear an apple floating in water.

Vacuum assisted biopsy system proposed by Biopsys involves sucking a breast lesion into a cannula and shearing off the captured edge of the lesion to obtain a biopsy sample. The device uses a vacuum to collect tissue into the side of an open tubular device, and then uses a rotating corer to cut the tissue collected. The rotating core is slidable within the tubular section and can be pulled back to remove the tissue collected in the rotating core. An additional stylet inside the rotating core can be used to push the tissue out of the core. The device can be rotated on its axis to remove a sample, 360 degrees around the central placement of the device. Typically, physicians sample six to eight cores. One advantage of this device is that the physician does not have to remove the device for additional biopsy samples. However,

the tumor itself must be re-engaged after every coring operation, which entails substantial effort in relocation and confirmation that the target suspect mass has been engaged by the side aperture. Tumors may be too tough to yield to the suction and deform as necessary to enter the side opening of the cannula. Doctors also currently use the device to take a circular sequence of cores by rotating the device about its long axis or by sideways movement of the suction head to take a line of cores.

After biopsy and analysis, the tumor must be treated with a separate device, as Biopsys teaches that their coring device should not be used for resection. Indeed, the device is not designed to perform resection with assurance that complete resection of a suspect mass has been accomplished. Mechanical cutting and disruption of the tissue structure and cancer cell dispersion (that is, tearing of the tissue around the cancer and movement of the cancer cells amongst normal tissue) will result in unintentional delivery of cancer cells into healthy tissue adjacent the lesion.

Summary

The devices and methods described below provide for diagnosis and treatment of tumors within the breast. The devices include structures which permit the surgeon to secure a suspect mass or tumor within the breast for an extended period of time and for several biopsies, coring procedures, or resections. The suspect mass or tumor is secured to a cannula for the entire diagnostic and treatment procedure, or subsets of the procedure such as biopsy or ablation. This allows the placement of the cannula with a single step utilizing methods such as ultrasound to guide the cannula toward the tumor.

The cannula includes a lumen adapted to be connected to a source of vacuum, which can be used to secure a breast lesion

to the cannula. A ring seal on the proximal end of the catheter permits biopsy needles, cryoprobes or other ablation devices to be inserted through the cannula and into the lesion while the vacuum on the cannula is maintained. In this manner, the needles and ablation devices may be inserted into the lesion while the lesion in held securely in place by the suction applied to the cannula.

Brief Description of The Drawings

Figure 1 illustrates the cannula adapted for use in securing a breast tumor during a biopsy or ablation procedure.

Figure 2 illustrates the biopsy needle in use with the cannula of Figure 1.

Figure 3 illustrates a multiple coring needle which may be used with the cannula of Figure 1.

Figure 4 illustrates the placement of a cryoprobe or other ablative device within the cannula of Figure 1.

Figure 5 illustrates a method of breast tumor ablation for tumors located near the skin.

Figure 6 illustrates a method of breast tumor ablation for tumors located near the skin.

Figure 7 illustrates and adaptation of the cannula to provide additional protection to the skin.

Detailed Description of the Inventions

Figure 1 illustrates the biopsy and treatment device adapted for use in securing a breast tumor during the biopsy and treatment procedure. The patient **1** and the patient's breast **2** and skin **3** of the breast are shown schematically. The tumor, lesion or other suspect mass **4** is located within

the breast, surrounded by soft tissue and fatty tissue. The tumor in this illustration is a well defined, hard mass ranging in size from 3 to 40 mm in diameter, typical of a benign palpable tumor or fibro-adenoma, although the device and method may be used to treat fibrocystic disease and other conditions. The device comprises a cannula **5** with a straight cut distal edge **6** adapted for insertion through a small incision in the skin overlying the tumor and a proximal end **7** which remains outside the breast. The proximal end of the cannula is fitted with hub **8** which serves as a handle and a manifold for the several connections to the cannula. This hub may be integral with the cannula or provided as a separate piece secured to the proximal end of the cannula. The cannula has a lumen **9** extending through the cannula from the distal edge to the proximal end of the cannula. On the hub, a vacuum connection **10** in the form of Luer fitting provides a fluid connection between the lumen of the cannula and a vacuum tube **11**. The vacuum hose may be connected to any source of vacuum or suction. On the proximal end of the hub, a valve **12** seals the cannula proximal end against air pressure but allows passage of the needles and probes used in the procedure. The valve may be a self-sealing silicone plug **13** provided with a slit **14** capable of accommodating the needles and probes by resiliently expanding and conforming around a needle or probe when a needle or probe is forced through the slit, and resiliently closing to an airtight seal when the needles or probes are removed. Thus, the valve allows for insertion of various instruments and elongate medical devices while maintaining the seal necessary to provide sufficient suction to hold the tumor. A stopper or cap **15** is provided for insertion into the slit when the valve is not occupied by a needle or probe to positively seal the valve. A backup valve, such as ball valve which opens to form a clear and straight lumen, may be placed in line before the valve 12 in place of

the stopper. The cannula is made of an acceptable biological material such as Teflon, carbon fiber, metal or metal composite for maximum strength with minimal wall thickness. The self-sealing valve is comprised of silicone or other material of similar resilience and conformability. An additional valve **16** may be added on the proximal handle, controlling a port **17** communicating between the vacuum lumen and the exterior of the cannula. The valve illustrated is merely a thumbslide mounted in a recess **18**. This valve may be used to break the vacuum established in the vacuum lumen to release a lesion from the distal tip of the device, or to bleed the vacuum from the lumen to lessen the suction on a lesion.

Figure 2 illustrates the cannula in use with a biopsy needle **20** in place within the lumen. A biopsy needle 20 fits within the lumen of the cannula and passes through the valve 12. The valve deforms and opens enough to allow the needle to pass through, yet still maintains a sufficiently airtight seal to maintain the vacuum within the cannula lumen. The needle has a sharp distal tip **21** which can pierce the tumor 4. The distal tip is shaped with a coring edge to collect tissue within the lumen **22** of the needle. As depicted in Figure 2, suction has been applied to the cannula lumen through the vacuum hose 11 and connection 10, thus drawing the tumor to the distal edge of the cannula and securely holding it in place. The biopsy needle has been inserted through the self-sealing valve and through the cannula lumen into and through the tumor. A small core of tumor tissue **23** has been forced into the lumen of the needle. The needle may now be removed and the core of tumor tissue extracted and analyzed for the presence of cancer cells. When the needle is removed, the suction is maintained on the cannula lumen and the tumor remains securely engaged with the cannula distal edge. The biopsy needle (or another) can then be inserted through the

cannula and into the tumor without having to relocate and reengage the tumor with the cannula. After all necessary biopsies have been taken, the sample tissue may be analyzed for the presence of cancer cells or other undesirable tissue for which ablation is indicated.

Figure 3 illustrates a multiple coring needle **24** for use with the system. This needle includes several coring lumens **25** opening at the distal end of the needle into coring edges **26**. The coring lumens are spaced in a circle about the circumference of the needle, and extend from the distal tip 21 of the needle proximally to the proximal end of the needle. It may be used in place of the single biopsy coring needle as illustrated in Figure 2. By providing suction to one or more of the lumens, the tumor is secured to the coring needle.

Figure 4 illustrates the use of an ablative device, such as cryoprobe, with the cannula. The cryoprobe **27** fits within the lumen of the cannula and passes through the valve 12, and the distal tip of the cryoprobe is forced into the tumor until the active freezing portion of the probe resides within the tumor. During placement of the cryoprobe, the vacuum is maintained within the lumen so that the tumor is securely engaged by the cannula. With the tumor secured by the vacuum, the cryoprobe may be easily forced into the tumor. The cryoprobe may be operated to ablate the tumor with cryogenic freezing as required to destroy the tumor. To operate the cryoprobe, liquid or gas cryogenic fluids (such as liquid nitrogen, or gaseous argon in combination with a Joule-Thomson cryostat in the probe tip) are passed through the probe, supplied from a cryosurgical control system (not shown). The operation of the cryoprobe creates an iceball **28** which encompasses the lesion 4, and cools the lesion to lethal cryogenic temperatures. Any ablation device may be used in place of the cryoprobe, including RF ablation probes,

microwave ablation probes, laser ablation probes, or focused ultrasound energy probes. Temperature sensors **29** may be mounted on the skin over the lesion in order to monitor skin temperature, so that the surgeon may avoid ablating the skin.

In use, the devices described above are used in place of traditional biopsy, coring and ablation devices. Prior to use, the patient is prepared and the breast is appropriately prepped and draped. The site is prepared using local anesthesia and, optionally, intravenous sedation. The patient is positioned on an operating table in the supine position, with the patient on her back. (If the procedure is accomplished under stereotactic guidance, the patient may be prone on a stereotactic table, exposing the breast below the table.) The breast is imaged, if not previously imaged, to determine the location of lesions. A small incision is made in the breast to allow the cannula to be easily inserted into the skin. The surgeon inserts the cannula into the patient's breast through the incision, pushes it into the breast until the distal edge of the cannula is proximate to the boundary of the tumor. An ultrasound scanner, MRI, stereotactic, mammographic, infrared or other imaging device is used to obtain an image of the breast, including the tumor and any device inserted into the breast, and the surgeon uses the display from the imaging device to assist in guidance of the cannula to the tumor. With the cannula distal edge in position near the tumor, the surgeon applies vacuum to the cannula through the side port on the cannula. The vacuum draws the tumor toward the cannula, and the cannula securely engages the tumor until the suction is broken at the end of the procedure. The surgical biopsy needle can be inserted through the cannula and into the tumor to retrieve a sample of tissue for analysis. Because coring can be accomplished without removing the portion of the tumor engaged by the cannula, or otherwise disrupting the suction between the

cannula and the tumor, several biopsy samples may be taken without having to relocate and re-engage the tumor.

Depending on the analysis of the biopsy (whether or not the samples obtained contain cancerous cells or other conditions), treatment of the tumor may be required. If analysis can be accomplished intra-operatively (that is, during a period of time in which it is feasible to keep the patient in the operating room and maintain the tumor engaged with the cannula), and indicates the presence of cancerous cells or other condition for which ablation is indicated, an ablation instrument can be inserted through the cannula and into the tumor. If so, the surgeon inserts an ablation instrument, such as a small caliber cryoprobe, into the tumor. Preferably, the surgeon inserts a cryoprobe through the valve and cannula and into the tumor, while maintaining suction on the cannula. The surgeon initiates cooling of the cryoprobe, and cools the tumor through one or more cycles of cooling to cryogenic temperatures and subsequent warming and thawing. A double freeze-thaw cycle is currently recommended. Each cycle consists of a 6 to 15 minute freeze followed by thawing until the internal cryoprobe temperature reaches 0°C (approximately 6 to 15 minutes). The device may also be used without regard to biopsy results. Patients prefer to have these lesions treated, even if they prove to be benign. In current practice, should biopsy results indicate the presence of cancer, the patient must return to the operating room shortly after the biopsy, undergo preparation, anesthesia, relocation of the lesion and ablation. Instead, the lesions may be ablated intraoperatively with the biopsy, immediately after biopsy and without interrupting the procedure to await the biopsy results. Should the biopsy prove negative for the presence of cancer, the patient will have received a substantially cosmetic treatment. Should the biopsy prove positive, the patient will have received a necessary

therapeutic procedure. In addition to the ablative procedure, the positive biopsy may indicate the need for additional monitoring and treatment.

For lesions deeper than 1 cm from the skin surface, the cryoprobe is advanced until the distal tip is located approximately in the center of the lesion or just beyond the lesion. For smaller lesions (<2cm diameter) the ice ball may grow beyond the margins of the tumor, while for larger lesions, the ice ball may remain within the confines of the tumor. The cryoprobe tip temperatures and skin mounted thermocouple readings are monitored throughout the ablation procedure. If the temperature of the skin overlying the cryoprobe measures below freezing, freezing operation of the cryoprobes should be paused until it returns to 10°C (the temperature at the edge of the ice ball edge is 0°C and exposure to such a temperature for the few minutes will not harm the skin, but caution should always be employed).

The procedure may be augmented with additional steps. Just prior to ablation treatment, prophylactic antibiotics can be administered at the surgeon's discretion. Just prior to cryosurgical ablation, cryogenic enhancement agents may be injected directed into the tumor through a hypodermic needle inserted through the valve and cannula and into the tumor while it is secured by suction to the cannula. During cooling operation of the cryoprobes, warm saline may be washed over the skin overlying the tumor and iceball to prevent freezing of the skin.

If the lesion being treated is close to the skin such that cryoablation of the lesion entails a danger of cryoablation of the overlying skin, several milliliters of a resorbable material such as sterile saline may be injected or inserted into the subcutaneous tissue between the skin and the

lesion. This will create a thermally protective mass or barrier layer between the tumor and the skin. Thermal protection may arise from insulative effect of the thermally protective mass or merely by the distension or separation of the skin away from the tumor and thus away from the iceball. As illustrated in Figure 5, where the tumor 4 is close to the skin 3, the thermally protective mass **30** is injected between the skin 3 and the subcutaneous fat **31** of the breast. When the cryoprobe 27 is operated to create the iceball, the ice-ball **32** either grows into the thermally protective mass or is inhibited in growth in the direction of the thermally protective mass (as illustrated by the non-spherical shape of the iceball in this illustration). This method basically distends the skin away from the iceball. This may also be accomplished by dissecting the skin away from the tumor with a balloon inserted between the skin and fat in the area overlying the tumor. Balloon dissection can be accomplished as illustrated in Figure 6. Here, a balloon **33** has been inserted subcutaneously between the tumor **4** and the overlying skin **3**. The balloon is inflated with air or other sterile gas, through inflation tube **34**, creating a good layer of insulation between the cryoprobe and the overlying skin.

Figure 7 illustrates and adaptation of the cannula to provide additional protection to the skin. The cryoprobe 27 is inserted through a side lumen **35** provided on the cannula 5. The breast lesion 4 is drawn by vacuum to the tip of the cannula. The cryoprobe is advances distally out of the side lumen until the freezing region underlies the lesion, and it operated to create the iceball **36**. The iceball extends superficially toward the skin and to encompass the lesion, and also extends posteriorly into the breast, where some healthy breast tissue is ablated but the overlying skin is not. This system and procedure also has the advantage that the lesion itself is not punctured, limiting the potential for seeding

due to the release of cancerous cells from the disruption of the tissue of the tumor.

The cannula illustrated above is preferably 10 to 20 cm in length and about 3 mm in diameter with an internal diameter of 2.8 mm, and a clearance of about .25 mm between the inner bore of the cannula and any device inserted through the cannula during suction. The cryoprobes may be Joule-Thomson probes, liquid cryogen probes, or probes of other designs. Various other ablative devices may be used in place of the cryoprobe, including laser ablation devices, RF ablation devices, chemical ablation catheters and any other ablative technology proposed for use to destroy tumors and lesions. The vacuum applied is preferably in the range of 14 to 21 inches of mercury vacuum.

The devices and methods illustrated above have been illustrated in relation to the treatment of tumors and lesions within the breast. However, they may be used to treat tumors and lesions throughout the body wherever the tumors which are difficult to secure and locate are encountered, and wherever nearby tissue must be protected from freezing. Thus the devices and methods may be used for tumors and lesions of the uterine tube (such as uterine fibroids), kidney, liver, prostate or brain.

Thus, while the preferred embodiments of the devices and methods have been described in reference to the environment in which they were developed, they are merely illustrative of the principles of the inventions. Other embodiments and configurations may be devised without departing from the spirit of the inventions and the scope of the appended claims.

We claim:

1. A device for performing a biopsy of a mass within the breast of a human patient, said device comprising:

a cannula adapted for insertion into the body of the patient, said cannula having a distal end and a proximal end, and a lumen extending through the cannula and defining a proximal opening and a distal opening in the cannula;

a fitting disposed on the proximal end of the cannula, said fitting adapted for connection to a vacuum source;

an airtight seal in the proximal opening of the cannula, said airtight seal permitting passage of needles and cryoprobes through the seal while substantially maintaining the airtight seal.

2. A system for treating or sampling of a mass within the breast of a human patient, said system comprising:

a cannula adapted for insertion into the body of the patient, said cannula having a distal end and a proximal end, and a lumen extending through the cannula and defining a proximal opening and a distal opening in the cannula;

a fitting disposed on the proximal end of the cannula, said fitting adapted for connection to a vacuum source;

an airtight seal in the proximal opening of the cannula, said airtight seal permitting passage of elongate medical devices through the seal while substantially maintaining the airtight seal;

a source of vacuum pressure operably connected to the fitting;

an elongate medical device capable of insertion through the airtight seal and into the cannula, said elongate medical device being long enough to extend from the proximal end of the cannula to a distance outside the distal opening of the cannula.

3. The system of claim 2 wherein the elongate medical device is a biopsy needle.

4. The system of claim 2 wherein the elongate medical device is a cryoprobe.

5. The system of claim 2 wherein the elongate medical device is an ablation device suitable for ablation of the mass.

6. A method of performing cryosurgery of a lesion in the body of a patient, said method comprising;

inserting a cannula into the body of the patient so that the distal edge of the cannula is proximate the lesion;

applying suction to a lumen of the cannula, thereby drawing the lesion toward the cannula;

inserting an ablative medical device through the lumen of the cannula and into the lesion;

operating the ablative medical device to ablate the lesion.

7. A method of performing cryosurgery of a lesion in the body of a patient, said method comprising;

inserting a cannula into the body of the patient so that the distal edge of the cannula is proximate the lesion;

applying suction to a lumen of the cannula, thereby drawing the lesion toward the cannula;

inserting a cryoprobe through the lumen of the cannula and into the vicinity of the lesion;

operating the cryoprobe to ablate the lesion.

8. A method of performing cryosurgery of a lesion in the breast of a patient, the lesion being located under a portion of overlying skin, said method comprising;

providing a cannula, said cannula having a distal tip and a lumen adapted for application suction to the distal tip thereof, and inserting the cannula into the body of the patient so that the distal tip of the cannula is proximate the lesion;

applying suction to a lumen of the cannula, thereby drawing the lesion toward the distal tip cannula;

inserting a cryoprobe into the breast and into the vicinity of the lesion;

operating the cryoprobe to ablate the lesion.

9. The method of claim 8 further comprising:

inserting the cryoprobe into the lesion by inserting it through the lumen of the cannula and then advancing the cryoprobe distally from the lumen of the cannula and into the lesion.

10. The method of claim 8 further comprising:

inserting the cryoprobe into the lesion.

11. The method of claim 8 further comprising:

inserting the cryoprobe into the breast in a position posterior to the lesion.

12. The method of claim 8 further comprising:

placing a thermally protective mass between the lesion and the overlying skin prior to operating the cryoprobe to ablate the lesion.

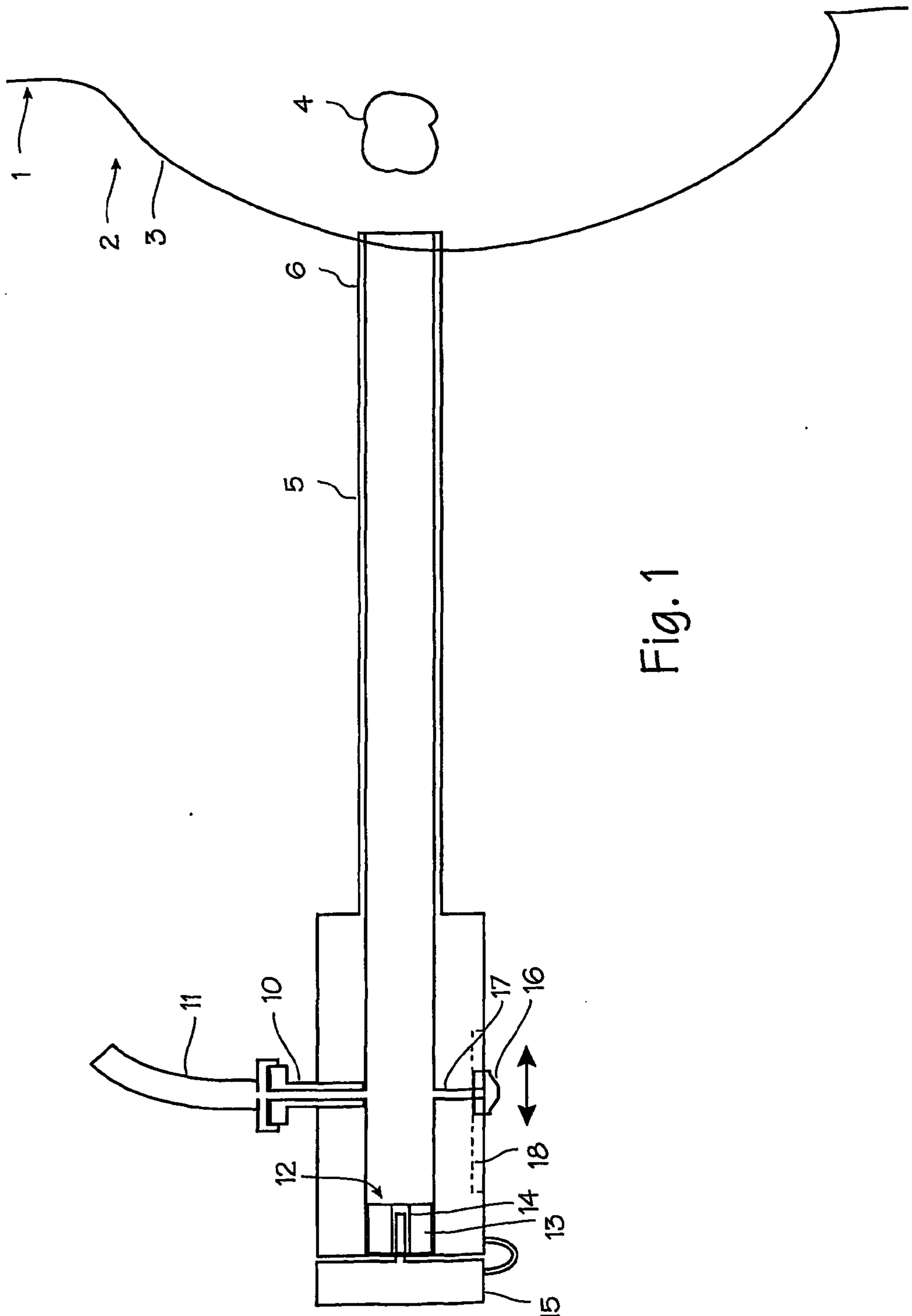

Fig. 1

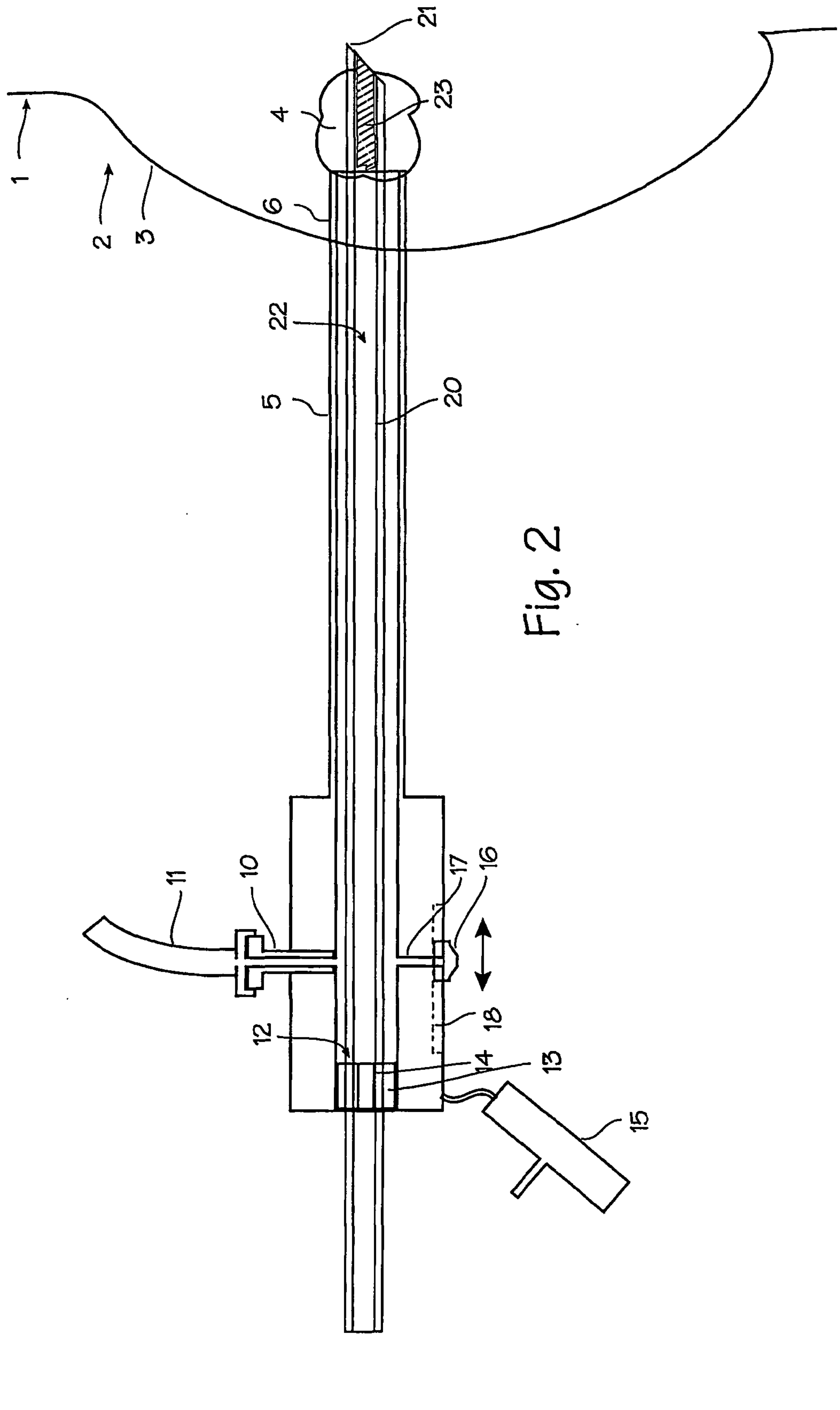

Fig. 2

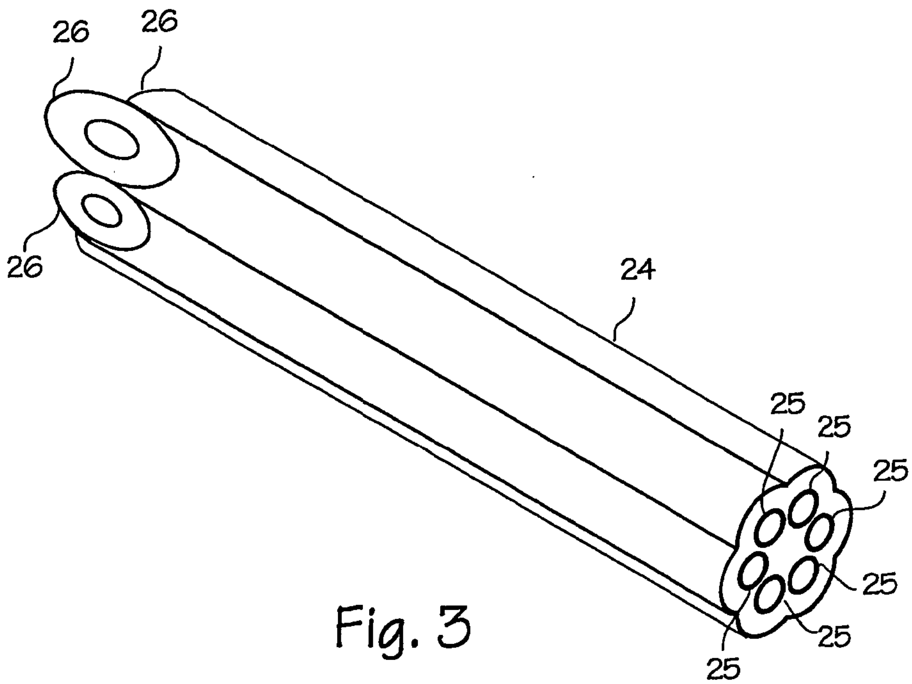

Fig. 3

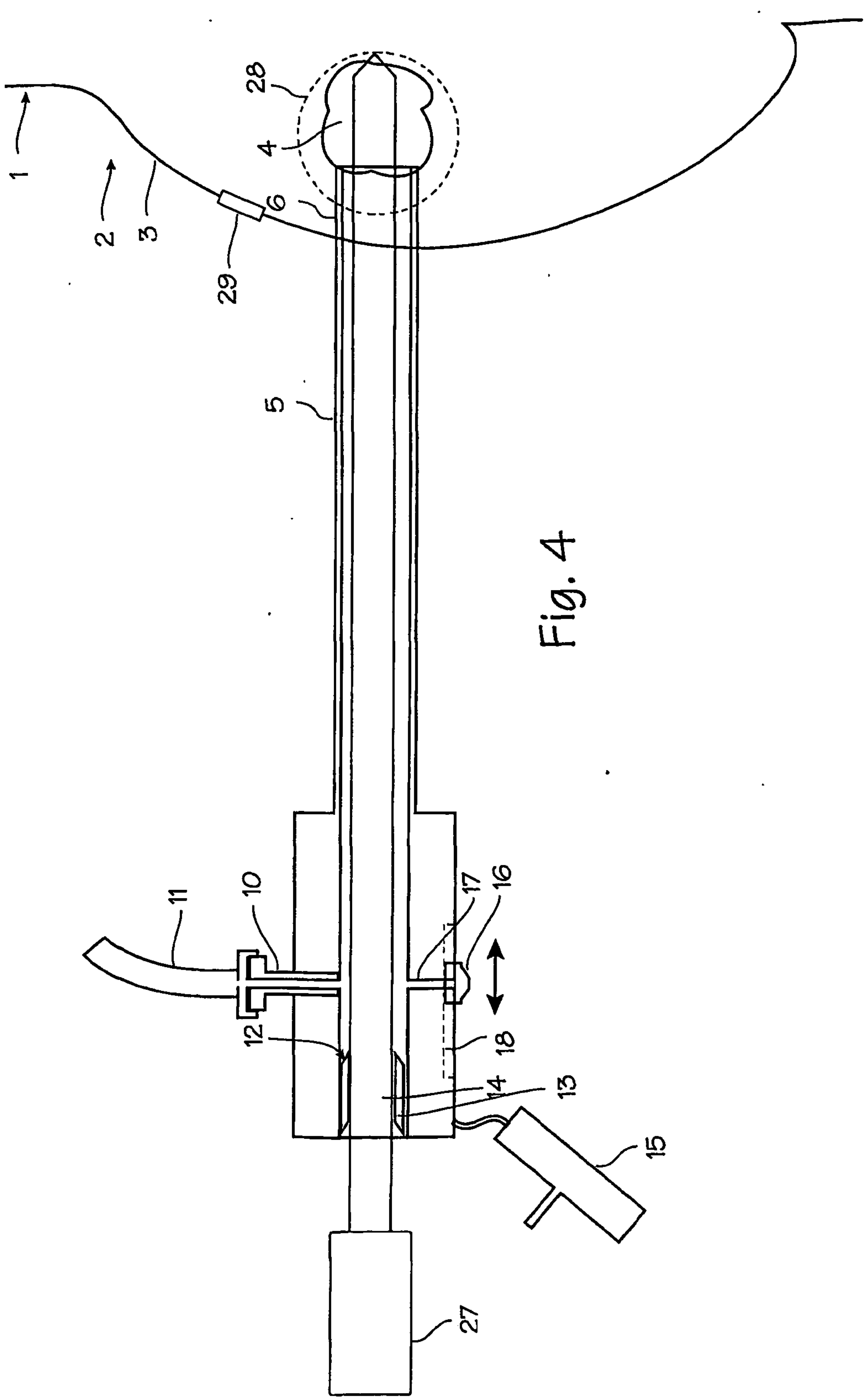

Fig. 4

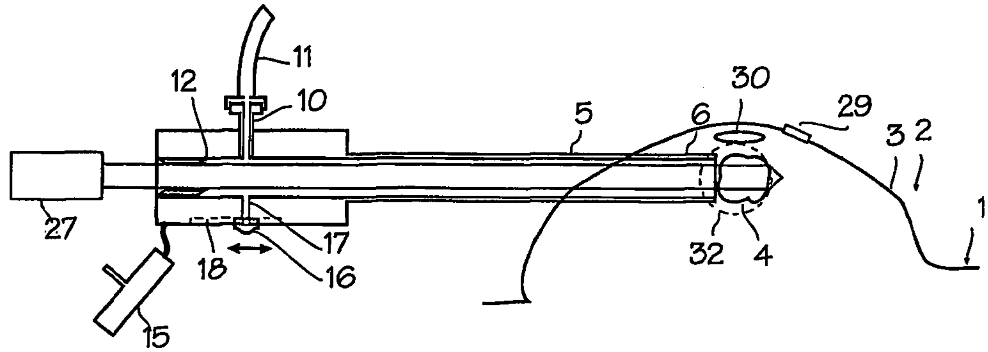

Fig. 5

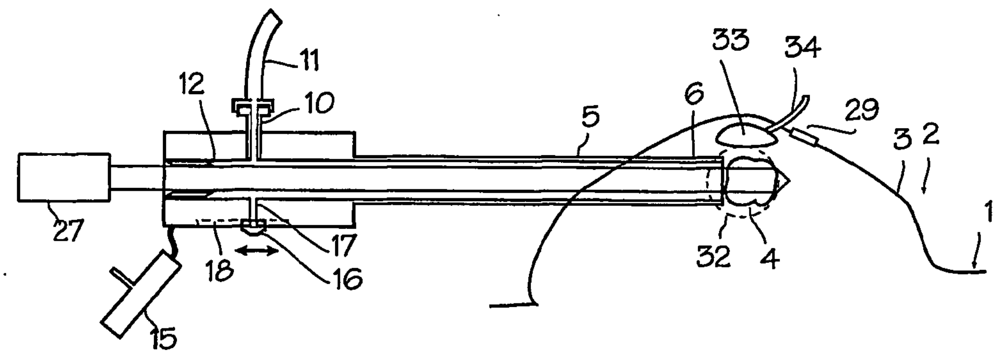

Fig. 6

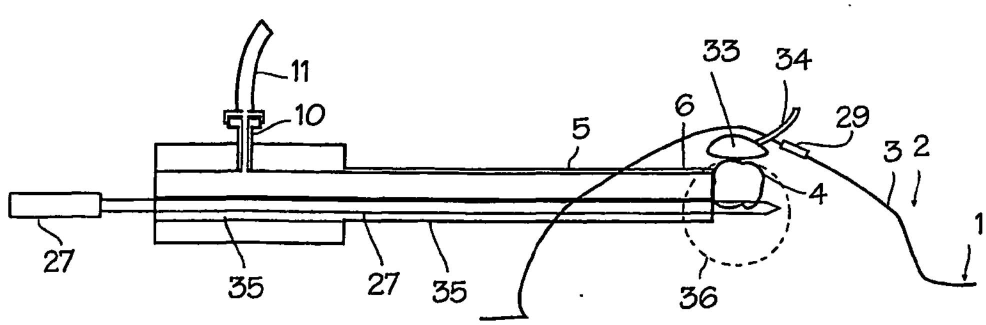

Fig. 7

INTERNATIONAL SEARCH REPORT

International application No.
PCT/US01/19454

A. CLASSIFICATION OF SUBJECT MATTER

IPC(7) :A61B 18/18
US CL :606/20
According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

U.S. : 606/1, 20-26; 600/565-567

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X -- Y	US 5,713,368 A (Leigh) 03 February 1998, whole document.	1-3 --- 4-7
Y	US 6,032,675 A (Rubinsky) 07 March 2000, whole document, figure 2.	4-7

☐ Further documents are listed in the continuation of Box C. ☐ See patent family annex.

*	Special categories of cited documents:	"T"	later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
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Date of the actual completion of the international search 05 SEPTEMBER 2001	Date of mailing of the international search report 06 NOV 2001
Name and mailing address of the ISA/US Commissioner of Patents and Trademarks Box PCT Washington, D.C. 20231 Facsimile No. (703) 305-3230	Authorized officer MICHAEL PEFFLEY Diane Smith f Telephone No. (703) 308-0858

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